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A new, water-resistant, film-forming, 30-second, one-step application iodophor preoperative skin preparation☆

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ABSTRACT
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Abstract

Background: A 1-step, film-forming iodophor preoperative skin preparation, Prevail-Fx, was developed. It forms a water-resistant film once dried on skin. To evaluate the partially water-soluble formulation, the testing method was validated with spore-challenge techniques and the efficacy was studied microbiologically and chemically. The importance of method validation and the presence of free iodine as criteria for product evaluation of partially water-soluble or water-insoluble skin preparations are discussed. **Methods:** The test methods outlined in the Federal Register, 21 CFR Parts 333 and 369 (Monograph), were used. Twenty-five American Type Culture Collection (Rockville, Md) species of organisms and 25 correspondent clinical isolates were tested in vitro. FDA In the clinical studies, the skin normal flora of the inguinal and abdominal sites were evaluated in a 30-second, single-step application. Betadine (Purdue Frederick Co, Norwalk, Conn) on scrub (7.5%) and Betadine solution (10%) were tested as controls in a 5-minute, 2-step application. **Results:** Prevail-Fx solution showed a broad spectrum in a minimum inhibitory concentration test. It delivered rapid bactericidal activity in a time-kill test, reducing 5 to 6 log of challenging organism in 3 minutes, as required by the Federal Drug Administration (FDA). In an in vivo clinical test with a single-step, 30-second application, Prevail-Fx effectively reduced greater than 4 log or greater than 3 log of normal skin flora in inguinal and abdominal testing sites, respectively. The bacterial levels remained significantly less than the baseline for 6 to 24 hours. These results meet and exceed the Federal Drug Administration's requirements. The efficacy of Prevail-Fx in a 30-second, single application is as effective as Betadine scrub and Betadine solution applied in a traditional 5-minute, 2-step scrubbing and painting. **Conclusion:** The Prevail-Fx film-forming formulation delivered rapid antimicrobial activity against a broad spectrum of micro-organisms in vitro and a rapid, persistent bactericidal activity in vivo in a 30-second, 1-step application against normal skin flora. This study also found that the spore-challenge validation of the testing methods and the evidence of free iodine are 2 indispensable criteria for the efficacy evaluation of the film-forming iodophor skin preparations. (Am J Infect Control 2001;29:370-6.)

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